In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 20-1900V UNPUBLISHED

REBECCA JOAN MILLER,

Petitioner,

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: September 29, 2022

Special Processing Unit (SPU); Findings of Fact; Onset and Statutory Six Month Requirement; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Amy A. Senerth, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Austin Joel Egan, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT AND CONCLUSIONS OF LAW DISMISSING TABLE CLAIM¹

On December 18, 2020, Rebecca Joan Miller filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleges that she suffered a left shoulder injury related to vaccine administration ("SIRVA") from an influenza ("flu") vaccine she received on October 21, 2019. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters, and Respondent has contested Petitioner's success in meeting the Table elements of a SIRVA-based claim.

¹ Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Although I find that Petitioner has more likely than not suffered the residual effects of her alleged vaccine-related injury for more than six months, Petitioner's Table SIRVA claim must still be dismissed because the evidentiary record does not support the conclusion that her pain onset occurred within 48 hours following administration of the flu vaccine. This leaves a possibly-meritorious causation-in-fact claim to be adjudicated.

I. Relevant Procedural History

On November 5, 2021, about 11 months after the case was initiated, Respondent filed a Rule 4(c) Report arguing that Petitioner had not established entitlement to compensation. ECF No. 19. Respondent argues that Petitioner cannot establish that the onset of her shoulder pain occurred within 48 hours after her flu vaccination. Rule 4 Report at 8. Respondent also argues that Petitioner cannot establish that she suffered the residual effects of her injury for more than six months as required by the Vaccine Act. Rule 4 Report at 9.3

After a brief period of negotiation, Petitioner filed a Motion for a Factual Ruling ("Mot.") on April 29, 2022. ECF No. 27. Respondent filed Respondent's Brief ("Resp.") on the same day. ECF No. 28.

The matter is now ripe for adjudication.

II. Factual History

Petitioner was an 18-year-old college volleyball player when she received an influenza vaccination in her left arm on October 21, 2019. Ex. 1 at 2; Ex. 9 at ¶3. Petitioner stated that she felt "discomfort" "immediately after receipt of the influenza vaccine." Ex. 9 at ¶3. Although she continued to experience "pain and very limited range of motion," she continued to play volleyball with her college team for the remainder of the season, explaining that she did not want to lose her starting position on the team. Ex. 10 at ¶6-7. Petitioner's last volleyball game of the season was on November 7, 2019. Ex. 10 at ¶7; Respondent's Ex. 1.

On November 11, 2019, Petitioner visited her athletic trainer complaining of left shoulder soreness. Ex. 8 at 16. The trainer, Ms. Pizer, recorded the injury date as November 7, 2019. *Id.* at 15. She returned to Ms. Pizer on November 18, 2019, and was referred to a doctor for evaluation. *Id.* at 16. A "Student & Sports Accident Claim Form" completed the same day noted that Petitioner "got a flu shot and then played a match for W. Volleyball. While she was playing she experienced pain in her left shoulder that is still going on today." Ex. 2 at 5. Petitioner reported left shoulder pain for two weeks and pain

³ Respondent further argues that Petitioner's injury may have been caused by a volleyball injury, however, that issue was not briefed and is not decided here. Rule 4(c) Report at 9.

with activities of daily living ("ADLs"). *Id.* at 6. The physician noted normal, but painful, active range of motion and referred Petitioner to physical therapy. *Id.*

The following day, November 19, 2019, Petitioner presented to physical therapy for an initial evaluation. Ex. 3 at 187. Petitioner reported that she "began having L shoulder pain a few weeks ago" after "getting a flu shot *shortly* before and thinks that may have correlated the pain." *Id.* at 189 (emphasis added). Petitioner also stated that she "was also playing volleyball so thought it was just soreness from that." *Id.* The physical therapist recorded the onset date as November 7, 2019. *Id.* at 187. On exam, Petitioner had rotator cuff weakness, and decreased active and passive range of motion. *Id.* at 190.

Petitioner returned to her university physician on December 2, 2019. Ex. 2 at 8. He noted continued pain with ADLs and positive impingement testing, and prescribed ibuprofen and continued physical therapy. *Id.* A little more than two weeks later, on December 19, 2019, Petitioner presented to an orthopedist, Dr. Mounif Rifka, for evaluation of her left shoulder pain. Ex. 5 at 22. Petitioner reported shoulder pain for two months "after she received a flu shot in that shoulder." *Id.* Dr. Rifka reviewed Petitioner's MRI and noted that her exam and MRI were "consistent with tearing of the teres minor." *Id.* at 23. He recommended rehab for six weeks and non-steroidal medication. *Id.* Petitioner returned to Dr. Rifka on February 20, 2020. *Id.* at 16. Dr. Rifka noted that Petitioner was "doing significantly better after completing physical therapy." *Id.* at 17. He stated that she "should continue to do a home exercise program but can return to volleyball." *Id.* He emphasized that Petitioner should start slowly and work her way back to full participation. *Id.*

Petitioner continued physical therapy through March 4, 2020, a total of 20 sessions. Ex. 8 at 28. The note from that visit indicated a plan to transition to a home exercise program in the next two to three weeks. *Id.* at 29. She was discharged from physical therapy on March 10, 2020. *Id.* at 15. At discharge, Petitioner had met all of her physical therapy goals except returning to full volleyball activity without pain. *Id.* On exam, Petitioner was pain free and had full range of motion, but continued to have "minor scapular winging with resistance." *Id.* Petitioner stated that, at the time of her discharge from PT, she still had weakness in her left shoulder, but she was unable to continue formal physical therapy due to the Covid-19 pandemic. Ex. 10 at ¶10.

On March 23, 2020, Petitioner was required to move out of her dorm room because her university shut down during the pandemic. Ex. 10 at ¶10. Petitioner recalled that she was not able to carry boxes during the move due to her shoulder injury, a fact recalled by her boyfriend as well. *Id.*; *See also* Ex. 12 at ¶6. Once she had moved home, Petitioner continued to do her home exercise program from physical therapy. Ex. 10 at ¶11; Ex. 11 at 5. Petitioner's mother also recalled that Petitioner had planned to continue physical

therapy, but was unable to because of strict Covid-19 restrictions, and favored her non-injured arm when completely household and personal tasks. Ex. 11 at ¶5.

On April 27, 2020, Ms. Pizer, the university athletic trainer, closed out Petitioner's shoulder injury in the relevant records. Ex. 8 at 15.

III. Applicable Legal Standards

The Vaccine Act requires that a petitioner demonstrate that "residual effects or complications" of a vaccine-related injury continued for more than six months. Vaccine Act §11(c)(1)(D)(i). A petitioner cannot establish the length or ongoing nature of an injury merely through self-assertion unsubstantiated by medical records or medical opinion. §13(a)(1)(A). "[T]he fact that a petitioner has been discharged from medical care does not necessarily indicate that there are no remaining or residual effects from her alleged injury." *Morine v. Sec'y of Health & Human Servs.*, No. 17-1013V, 2019 WL 978825, at *4 (Fed. Cl. Spec. Mstr. Jan. 23, 2019); see also Herren v. Sec'y of Health & Human Servs., No. 13-1000V, 2014 WL 3889070, at *3 (Fed. Cl. Spec. Mstr. July 18, 2014).

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19. And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] ... did in fact occur within the time period described in the Vaccine Injury Table." *Id.*

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

A. Onset

Although I acknowledge that the standard applied to resolving onset for an alleged Table SIRVA is liberal and will often permit a determination in a petitioner's favor, especially in the absence of contemporaneous and direct statements in the medical records to the contrary, not every case can be so preponderantly established. Ultimately, the resolution of such fact issues involves weighing different items of evidence against the overall record.

Here, Petitioner's claims of onset contradict a significant record created very near-in-time to vaccination that the onset of her pain occurred longer than 48 hours after her vaccination. There is no dispute that Petitioner received her flu vaccination on October 21, 2019, meaning that the onset of her shoulder pain must have begun by October 23, 2019 for her to establish the required timeline for a Table claim. However, in seeking treatment, Petitioner consistently reported the onset of her left shoulder pain between November 4 and 7, 2019.

For example, at her first post-vaccination visit to the university athletic trainer, the date of injury was recorded as November 7, 2019. Ex. 8 at 15. At her first visit with a doctor on November 18, 2019, Petitioner reported pain "for two weeks" – placing onset on or about November 4, 2019. At her initial physical therapy evaluation on November 19, 2019, Petitioner reported pain for "a few weeks" and beginning "shortly" after her flu shot. Ex. 3 at 187. Three weeks prior to November 19, 2019 was October 29, 2019, eight days after Petitioner's flu vaccination. Generally, information contained in contemporaneously created medicals records is considered trustworthy because it is provided close in time to the events in question for the purpose of obtaining medical care. *Cucuras*, 993 F.2d at 1528. Even when the information in a record was provided to a treater by the petitioner, it is still considered more trustworthy than allegations made at the time a petition is filed, or thereafter. Here, multiple medical records created approximately one month after vaccination describe Petitioner's shoulder pain as beginning approximately two weeks after her vaccination.

Although Petitioner states that her pain began immediately upon vaccination and did not resolve, a fact corroborated by her mother her boyfriend, she reported the onset of her injury as approximately two weeks later to at least three separate medical providers within a month of her vaccination.⁴ There are situations in which compelling testimony

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⁴ Petitioner later reported an onset of "2 months" ago at her orthopedist visit on December 19, 2019, which suggests an onset around October 19, 2019 (before her vaccination). Ex. 5 at 22. Even though this report is closer to the required 48-hour timeframe, it fails to provide sufficient specificity to overcome the previous records.

may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (*quoting Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992)). But here, the records nearest in time to Petitioner's vaccination are clear and consistent, and together preponderate against a 48-hour onset. Petitioner's testimonial statements do not undercut that determination.

Accordingly, I find Petitioner has not preponderantly established that onset of his pain occurred within 48 hours of vaccination – meaning that she cannot proceed in this action with a Table SIRVA claim, at a minimum.

B. Severity

Only a Table SIRVA claim requires a petitioner to prove onset of pain within 48 hours of vaccination. Thus, Ms. Miller's inability to establish this element is not automatically fatal to her claim, if recast as a causation-in-fact claim. However, Respondent also contests a claim requirement that applies to any form of Program claim: the need to demonstrate that the relevant vaccine injury continued for more than six months. Resp. at 12.

In this case, Petitioner received her vaccination on October 21, 2019. Ex. 1 at 2. It is undisputed that Petitioner's last formal medical record relating to her injury was her physical therapy discharge summary on March 10, 2020 – 42 days short of the six-month period. In order to establish at least six months of residual effects, Petitioner must establish that her residual symptoms continued until at least April 21, 2020.

At the time of her last physical therapy treatment on March 4, 2020, Petitioner continued to demonstrate a need to continue formal physical therapy, as the therapist noted that Petitioner fatigued with exercise. Ex. 8 at 29. The plan was to transition to a home exercise program in another few weeks and to begin athletic conditioning. *Id.* However, the plan was disrupted by the Covid-19 pandemic and Petitioner was discharged from physical therapy on March 10, 2020, despite continuing weakness in her shoulder. *Id.* at 15; Ex. 10 at ¶10. On March 23, 2020, Petitioner continued to experience symptoms of her injury, as she was unable to carry boxes while moving out of her dorm when her university shut down during the early days of the pandemic. Ex. 10 at ¶10; Ex.

12 at ¶6. Thus, the severity requirement in this case requires a finding that Petitioner had not yet fully recovered from her injury approximately four weeks after leaving school.

Although there is little evidence – and no medical records - regarding Petitioner's symptoms after March 23, 2020, Petitioner's mother stated that after moving home, Petitioner continued to perform her home exercise program daily, and continued to favor her non-injured arm in completing household and personal tasks. Ex. 11 at 5. After consideration of the entire record, I find that the evidence preponderates – just barely – in Petitioner's favor on this issue. While Petitioner and her mother did not state a specific end date for her symptoms, it is simply more likely than not that Petitioner continued to experience residual effects, even if minor, for four weeks after leaving school. This is particularly true when considering that, due to the pandemic, Petitioner was left to treat the residual effects of her injury without the assistance of continued formal physical therapy, as was planned. Finally, the analysis requires a balance of the absence of record evidence of continued treatment with the equal absence of record evidence that the injury had completely resolved prior to April 21, 2020. Such a circumstance creates a "tie" in evidence that, in the Vaccine Program, is resolved in favor of Petitioner. See Roberts v. Sec'y of Health & Human Servs., No. 09-0427V, 2013 WL 5314698, at 10 (Fed. Cl. Spec. Mstr. Aug. 29, 2013).

For all of the above reasons, I find that there is preponderant evidence that Petitioner suffered the residual effects of her left shoulder injury for more than six months.

Conclusion

Petitioner has established that she suffered the residual effects of her alleged vaccine-related injury for at least six months. However, as I also find that Petitioner has not preponderantly established that the onset of her shoulder pain occurred within 48 hours of vaccination, she cannot proceed in this action with a Table SIRVA claim. Accordingly, Petitioner's Table SIRVA claim is dismissed. The case will be reassigned to a Special Master outside of the Special Processing Unit ("SPU").

IT IS SO ORDERED.

<u>s/Brian H. Corcoran</u> Brian H. Corcoran Chief Special Master